REMARKS

Claims 1 – 21 are pending in this application.

Claims 1 – 21 have been rejected.

Rejections of Claims 1 – 17 and 19 - 22 under 35 U.S.C. § 103

Claims 1 – 17 and 19 – 21 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,154,677 ("Leysieffer '677"). These rejections are respectfully traversed.

Leysieffer '677 discloses various embodiments of an implantable device with a charging current feed arrangement which has a receiving coil. In one embodiment, the implantable device has a main module 56 with a housing 72 containing electronics and a battery (column 3, line 63 – column 4, line 22). The implantable device includes other modules, such as sensor 60 and actuator 70, which are coupled to the main module 56 via coupling element 64 (column 3, line 4 – column 4, line 19). A receiving coil 106 is a part of a unit 105 which is covered by a polymer jacketing 104 and "connected mechanically tightly" to the main module housing 72 "on the side facing away from coupling element 64" (column 4, lines 49 – 52). But in this and other embodiments illustrated in Figures 2 – 7 and 9 the receiving coil 106 is not centrally located on a housing proximal face of implantable medical device. Rather, in each case, receiving coil 106 is "attached laterally to the main housing" (column 6, line 38), as in Figures 1 – 4, and 7, is located on a side face as in Figures 5 and 6, or is located in a module entirely separate from the housing of the implantable medical device as in Figure 9.

In an embodiment illustrated in a side-view of Figure 8, the receiving coil 106 is "seated on a broad side of the main module housing 132" (column 6, line 40). While the side profile suggests that the receiving coil 106 is centrally located in one dimension, i.e., laterally from the perspective of the drawing, Leysieffer '677 does not show, disclose or suggest that the receiving coil is centrally located in the other dimension, i.e., depth from the perspective of the drawing. As such, it would be speculation to assert that the disclosure of Figure 8 is that the receiving coil is centrally located. Leysieffer '677 merely discloses that the receiving

coil is seated on a broad side of the housing. Moreover, Leysieffer '677 discloses that when the receiving coil is seated on a broad side of the housing that other components such as battery 90 are not located in the housing 132. Thus, Leysieffer '677 does not show, disclose or suggest that the receiving coil is located on a housing proximal face while the battery is located in the housing.

In contrast, independent claim 1 clearly and explicitly requires "a rechargeable power source carried in the housing interior cavity" (claim 1, lines 7 – 8) and a "recharging coil centrally located and substantially carried on the housing proximal face" of the housing of the implantable medical device (claim 1, lines 9 – 10). Claim 21 recites "a rechargeable power source carried in the housing interior cavity" (claim 21, lines 7 – 8) and a "means for recharging carried on the housing proximal face" and "means for attaching the means for recharging to a position centrally located and substantially carried on the housing proximal face" (claim 21, lines 9 – 12). Leysieffer '677 does not show, disclose or suggest a recharging coil centrally located and substantially carried on a housing proximal face, disclosing only that it may be carried on a broad side of the housing. Moreover, Leysieffer '677 plainly discloses that when the receiving coil is located on the broad side of the housing, the battery is not then located in the housing. The Examiner essentially admits as much saying "absent any teaching or unexpected results, merely changing the location of the coil on the exterior face of the housing to a central location would be an obvious design choice" (Office Action mailed February 26, 2008, page 4, lines 13 – 15).

However, as established in the Declaration of John Kast under 37 C.F.R. 1.132, filed herewith, centrally locating the recharging coil on a proximal face of the house actually does produce an advantageous result not anticipated, shown nor suggested in the cited art. Kast is the inventor and has extensive experience in energy transfer to implantable medical devices (Kast Affidavit, paragraphs [1] – [3]). Kast obtained and tested an implantable medical device in an engineering lab to simulate the implantation of an implantable medical device in a human (Kast Affidavit, paragraphs [4] – [5]). A variety of secondary recharging coils were utilized, with the location of the external primary recharging coil being varied with respect to the secondary recharging coil (Kast Affidavit, paragraph [6]). The power efficiency and charging current for the secondary coil were plotted for varying amounts of misalignment of

the external primary recharging coil relative to the secondary recharging coil. The resultant data illustrates the importance of locating the external primary recharging coil as directly concentrically as possible with respect to the secondary recharging coil; efficiency and charging current drop off significantly if the two coils are not directly concentrically aligned (Kast Affidavit, paragraphs [7] and [8]).

An implantable medical device was also tested in a cadaver lab to simulate the implantation of the implantable medical device in a human (Kast Affidavit, paragraph [9]). Since the recharging coil is implanted, it is sometimes difficult to determine the exact location to place or locate the external coil so that the external coil is most closely aligned with the secondary coil. This is because the internal recharging coil can not be directly observed by the patient. An implanted medical device will typically result in a bump or slight protrusion of the skin of the patient at the site of implantation. Such bump or slight protrusion may be observed by the patient, perhaps visually but more often tactilely, i.e., through palpation of patient tissue. Thus, the patient may be able to reasonably establish the location of the implanted device. In the cadaver lab testing, multiple people determined the location of the implanted implantable medical device by palpation of the tissue of the cadaver and placed the external primary recharging coil on that basis (Kast Affidavit, paragraph [10]). A locating piercing fixture was then used to determine the alignment of the external primary recharging coil relative to the implantable medical device (Kast Affidavit, paragraph [11]). The average position chosen by palpation was approximately in the center of the implantable medical device (Kast Affidavit, paragraph [12]).

The data from Kast Affidavit, paragraph [7] establishes that optimal efficiency can be achieved by concentric alignment of the external primary recharging coil with the implanted secondary recharging coil, and the data from Kast Affidavit, paragraph [12] indicates that the average position of the primary recharging coil relative to the implantable medical device based on skin palpation is in the center of the device. Thus, the Kast affidavit establishes the importance of the secondary recharging coil being centrally located with respect to the proximal face of the implantable medical device, as doing so could, on average, achieve the greatest concentricity between the external primary recharging coil and the secondary recharging coil, and thus the greatest efficiency of energy transfer.

This highly advantageous result is not shown in the prior art. Nothing in Leysieffer '677 discloses such a central location, provides any suggestion of such a central location nor provides any glimpse of the importance of such a central location. Moreover, to the extent that Leysieffer '677 discloses carrying the receiving coil on the broad side of the housing, Leysieffer '677 is apparently compelled to reduce the internal volume in the housing by removing the battery, as shown in Figure 8. Even in such an embodiment, Leysieffer '677 does not show, disclose or suggest that the receiving coil is centrally located on both axes. Thus, it is respectfully submitted that the central location of the recharging coil may be critical to establishing and/or maintaining efficiency of energy transfer and directly leads to the unexpected result of providing a higher efficiency of energy transfer while maintaining the power source within the housing. This result is not shown nor suggested in Leysieffer '677 nor in any of the other cited art.

Moreover, to the extent that Leysieffer '677 addresses the physical location of the receiving coil, Leysieffer '677 actually teaches away from locating a recharging coil centrally on a proximal face of an implanted device by specifically disclosing a housing having a higher section (91) which is designed to hold the battery (90) and a reduced-height section offset to one side of the implanted device designed to hold electronic modules (74 and 76). Receiving coil (106) is attached in the space formed by the housing gradation, which is necessarily offset from the implanted device (see, for example, column 5, lines 28 – 42 and Figures 5 and 6). Leysieffer '677 specifically teaches the benefits of offsetting the coil to one side of the proximal face of the device and, therefore, teaches away from the presently claimed invention. But as can be seen, even if the user were to know that the recharging coil was located on one side of the implanted device (and this point is not conceded because it has not been shown nor discussed in the art), it has not been shown how the user/patient is to know on which side of the device to locate the external coil, as the resulting proximal face disclosed in Leysieffer '677 is, essentially, flat. This would usually, in the absence of blind luck, result in a non-optimal recharge session when the Leysieffer '677 device is used.

With such an advantageous result realized by centrally locating the secondary recharging coil, as shown by the research and testing by Kast, if it were simply a matter of design choice, as asserted in the Office Action, then certainly the cited art would have done

so. The fact that the cited art did not appreciate these advantageous results attests to the fact that centrally locating the secondary recharge coil on the housing proximal face is a significant and unanticipated advance in the art.

As Leysieffer '677 fails to show, disclose or suggest all of the limitations of claims 1 and 21, it is respectfully submitted that the rejections of claims 1 and 21 under 35 U.S.C. § 103(a) as being obvious over Leysieffer '677 are improper and should be withdrawn.

Claims 2, 3, 5 – 17, 19 and 20 depend from claim 1, and as such incorporate all of the subject matter of claim 1. In addition, claims 2, 3, 5 – 17, 19 and 20 recite additional patentable subject matter. Because the rejection of claim 1 is improper, and because of the additional patentable subject matter, it is respectfully submitted that the rejections of claims 2, 3, 5 – 17, 19 and 20 under 35 U.S.C. § 103(a) as being unpatentable over Leysieffer '677 are improper and should be withdrawn.

Rejection of Claim 18 under 35 U.S.C. § 103

Claim 18 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,154,677 ("Leysieffer '677") in view of U.S. Patent No. 5,279,292 ("Baumann et al '292"). These rejections are respectfully traversed.

The above discussion of claim 1, from which claim 18 depends, and Leysieffer '677 is incorporated in its entirety.

Baumann et al '292 discloses a charging system for implantable hearing aids and tinnitus maskers. The system comprises an implantable medical device with a recharging coil, a rechargeable power source, and electronics, all contained within the housing of the implantable medical device (column 3, lines 4 – 33). However, Baumann et al '292 does not show, disclose or suggest a recharging coil centrally located and substantially carried on a proximal face of the housing. As noted above, Leysieffer '677 does not disclose the feature of centrally locating the recharging coil with respect to the proximal face of the implantable medical device. Baumann et al '292 has been cited solely for the teaching of a telemetry coil carried in the interior cavity of the housing of the implantable medical device. Baumann et al '292 does not show, disclose nor suggest a recharge coil "centrally located and substantially

carried on the housing proximal face" of the implantable medical device. All of the arguments presented above with respect to Leysieffer '677 apply equally well to Baumann et al '292.

As neither Leysieffer '677 nor Baumann et al '292, nor any combination of Leysieffer '677 and Baumann et al '292, show, disclose or suggest all of the limitations of claim 18, it is respectfully submitted that the rejection of claim 18 under 35 U.S.C. § 103(a) as being obvious over Leysieffer '677 in view of Baumann et al '292 is improper and should be withdrawn.

Summary

In view of the amendments made and the arguments presented, claims 1 – 21 should be allowable, this application should be in condition for allowance and a notice to that effect is earnestly solicited.

Respectfully Submitted,

JOHN E. KAST ET AL.

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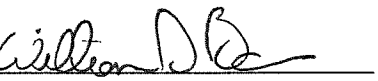

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